**UNITED STATES DISTRICT COURT**
**WESTERN DISTRICT OF LOUISIANA**
**LAFAYETTE DIVISION**

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| **PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA** | **CASE NO. 6:23-CV-00997** |
| **VERSUS** | **JUDGE ROBERT R. SUMMERHAYS** |
| **LIZ MURRILL** | **MAGISTRATE JUDGE CAROL B. WHITEHURST** |
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| **ASTRAZENECA PHARMACEUTICALS LP** | **CASE NO. 6:23-CV-01042** |
| **VERSUS** | |
| **LIZ MURRILL** | |
| ********** | ********** |
| **ABBVIE, INC., ET AL** | **CASE NO. 6:23-CV-01307** |
| **VERSUS** | |
| **LIZ MURRILL** | |
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**MEMORANDUM RULING**

Presently before the Court in three related matters are: (1) Motions for Summary Judgment filed by Plaintiffs AstraZeneca Pharmaceuticals LP ("AstraZeneca"), AbbVie, Inc. ("AbbVie"), and Pharmaceutical Research and Manufacturers of America ("PRMA") (collectively, "Plaintiffs");[1] (2) Cross Motions for Summary Judgment[2] by defendant, Liz Murrill; and (3) Cross Motions for Summary Judgment[3] by the intervenor, Louisiana Primary Care Association

[1] ECF No. 21 in 6:23-cv-997; ECF No. 21 in 6:23-cv-1042; and ECF No. 28 in 6:23-cv-1307.
[2] ECF No. 41 in 6:23-cv-997; ECF No. 43 in 6:23-cv-1042; and ECF No. 49 in 6:23-cv-1307.
[3] ECF No. 44 in 6:23-cv-997; ECF No. 45 in 6:23-cv-1042; and ECF No. 61 in 6:23-cv-1307.

("LPCA"). The Court held a consolidated hearing on the various motions on June 6, 2024. After oral arguments, the Court took all the motions under advisement.

## I.
## BACKGROUND

Two pharmaceutical companies—AstraZeneca and AbbVie—and Pharmaceutical Research and Manufacturers of America filed the three above-captioned cases challenging Louisiana's recently enacted Act 358 on the grounds, *inter alia*, that it is preempted by the federal Section 340B discount drug program, located at 42 U.S.C. § 256b, *et seq*. Section 340B of the Public Health Service Act was enacted as part of the Veterans Health Care Act of 1992 and requires pharmaceutical companies to offer discounts on covered outpatient drugs to specified "safety-net" health care providers as a condition of the companies' voluntary participation in the Medicaid and Medicare Part B programs.[4] The safety-net hospitals and clinics that are eligible to participate in the Section 340B program are defined as "covered entities," and the eligibility criteria for covered entities are set forth in the statute.[5] The Section 340B program is administered by the Health Resources and Services Administration ("HRSA"), which is a component of the federal Department of Health and Human Services ("HHS").

The present dispute centers on the role of "contract pharmacies" in the Section 340B program. The summary judgment record reflects that many covered entities, including LPCA's members, cannot afford to establish and operate "in-house" pharmacies but instead must enter into contracts with independent, private pharmacies to dispense discounted drugs to their patients.[6] The

[4] 42 U.S.C. §§ 256b(a)(1), 1396r-8(a)(1).
[5] *Id*. § 256b(a)(4) (listing the healthcare providers eligible to participate in the program).
[6] *See* ECF No. 44-4 at 4-5, *Pharmaceutical Research and Manufacturers of America v. Liz Murrill*, Civ. No. 6:23-cv-997 (W.D. La. July 27, 2023) ("*PRMA*"); *see also* Notice Regarding Section 602 of the Veterans Health Care Act of 1992; Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,550 (Aug. 23, 1996) (recognizing that many 340B covered entities cannot afford to "expend precious resources to develop their own in-house pharmacies . . . .").

record also includes evidence that some covered entities service large geographic areas and that contract pharmacies assist those providers in serving a dispersed population.[7]

In a 1996 guidance document, HHS permitted covered entities to contract with one outside pharmacy if they did not maintain an in-house pharmacy to distribute discounted drugs under the Section 340B program.[8] In 2010, HHS modified its guidance on contract pharmacies and permitted covered entities to contract with an unlimited number of outside pharmacies.[9] As a result of this change and guidance, the number of contract pharmacies increased from approximately 1,300 in 2010 to approximately 20,000 in 2017.[10]

Beginning in 2020, a number of pharmaceutical companies imposed restrictions and limitations on the distribution of Section 340B discounted drugs to contract pharmacies.[11] In response, HHS issued an opinion stating that "covered entities under the 340B program are entitled to purchase covered outpatient drugs at no more than the 340B ceiling price—and manufacturers are required to offer covered outpatient drugs at no more than the 340B ceiling price—even if those covered entities use contract pharmacies to aid in distributing those drugs to their patients."[12] HHS went on to conclude that the "plain meaning" of Section 340B precluded participating pharmaceutical companies from restricting or otherwise limiting contracts between covered entities and outside, retail pharmacies.[13] Plaintiff AstraZeneca and other pharmaceutical companies challenged HHS' contract pharmacy opinion and, ultimately, prevailed in the Third

[7] *Id.*
[8] *Id.*
[9] Notice Regarding 340B Drug Pricing Program – Contract Pharmacy Services, 75 Fed. Reg. 10,272 (Mar. 5, 2010).
[10] U.S. Gov't Accountability Office, Drug Discount Program: Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement 2 (June 2018), https://www.gao.gov/assets/700/692697.pdf (last viewed September 10, 2024).
[11] *See, e.g.,* Sanofi Policy, SANOFI (Feb. 1, 2021), https://340besp.com/sanofi-policy-2021-02-02- 09_18_19.pdf.
[12] *AstraZeneca Pharms. LP v. Becerra*, 543 F. Supp. 3d 47, 52-53 (D. Del. 2021).
[13] *Id.*

Circuit in *Sanofi Aventis U.S. LLC (Sanofi) v. U.S. Dep't of Health and Human Services*.[14] In that case, the Third Circuit held that Section 340B is silent with respect to contract pharmacies and, therefore, HHS lacked the statutory authority to issue its opinion restricting the ability of participating pharmaceutical companies to adopt policies on the distribution of discounted drugs to contract pharmacies.[15]

During the *Sanofi* litigation, some states began to enact legislation governing the distribution of 340B drugs to contract pharmacies. In 2021, Arkansas became the first state to successfully pass a law addressing this issue.[16] PhRMA challenged the Arkansas Act on the basis of preemption and on March 12, 2024, the Eighth Circuit held that the Arkansas Act was not barred by preemption.[17] In 2023, Louisiana enacted La. R.S. 40:2881 *et seq*. ("Act 358"), which prevents pharmaceutical companies from restricting contract pharmacy arrangements made by Section 340B covered entities. Louisiana's Act 358, provides that:

> A. A manufacturer or distributor shall not deny, restrict, prohibit, or otherwise interfere with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity and is authorized under such contract to receive and dispense 340B drugs on behalf of the covered entity unless such receipt is prohibited by the United States Department of Health and Human Services.
>
> B. A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.[18]

Act 358 provides that a violation of these provisions is considered a violation of the Louisiana Unfair Trade Practices and Consumer Protection Law, La. R.S. 51:1401 ("LUTPA").[19] Importantly, § 40:2886(B)(1) provides that "Nothing in this Chapter is to be construed or applied

[14] 58 F.4th 696 (3d Cir. 2023).
[15] *Id.* at 703-706.
[16] *See* Ark. Code Ann. § 23-92-604.
[17] *PhRMA v. McClain*, 95 F.4th 1136 (8th Cir. 2024).
[18] La. R.S. § 40:2884.
[19] *Id*. § 40:2885.

to be in conflict with . . . [a]pplicable federal law and related regulations." Act 358 grants the Louisiana Attorney General enforcement authority over LUTPA violations including violations of the Act.[20] That authority includes the power "[t]o investigate, conduct studies and research, [] conduct public or private hearings . . . otherwise investigate complaints [and] institute legal proceedings" concerning acts or practices declared unlawful under LUTPA.[21]

The three above-captioned lawsuits have been filed against Liz Murrill in her official capacity as Attorney General for the State of Louisiana. In 6:23-cv-997, Pharmaceutical Research and Manufacturers of America ("PRMA") alleges that Act 358 is unconstitutional based upon preemption and vagueness. In 6:23-cv-1042, AstraZeneca Pharmaceuticals LP argues that Act 358 is unconstitutional based upon preemption and a violation of the Contracts Clause. In 6:23-cv-1307, AbbVie, Inc., et al ("AbbVie") assert that Act 358 is unconstitutional based upon preemption, vagueness and a violation of the Takings Clause. Louisiana Primary Care Association has intervened as a defendant in each of the three cases. Based upon the similar and overlapping issues, the Court consolidates the ruling in this matter and directs that the ruling be filed into each of the three cases.

## II.
## LAW AND ANALYSIS

### A. Summary Judgment Standard.

"A party may move for summary judgment, identifying each claim or defense–or the part of each claim or defense–on which summary judgment is sought."[22] "The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and

[20] *Id.* § 51:1404.
[21] *Id.*
[22] Fed. R. Civ. P. 56(a).

the movant is entitled to judgment as a matter of law."[23] "A genuine issue of material fact exists when the evidence is such that a reasonable jury could return a verdict for the non-moving party."[24] As summarized by the Fifth Circuit:

> When seeking summary judgment, the movant bears the initial responsibility of demonstrating the absence of an issue of material fact with respect to those issues on which the movant bears the burden of proof at trial. However, where the nonmovant bears the burden of proof at trial, the movant may merely point to an absence of evidence, thus shifting to the non-movant the burden of demonstrating by competent summary judgment proof that there is an issue of material fact warranting trial.[25]

When reviewing evidence in connection with a motion for summary judgment, "the court must disregard all evidence favorable to the moving party that the jury is not required to believe, and should give credence to the evidence favoring the nonmoving party as well as that evidence supporting the moving party that is uncontradicted and unimpeached."[26] "Credibility determinations are not part of the summary judgment analysis."[27] Rule 56 "mandates the entry of summary judgment . . . against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof."[28]

**B. <u>Preemption</u>.**

The Court first addresses Plaintiffs' claims that the statutory and regulatory framework of the Section 340B program preempts Louisiana's Act 358. Federal preemption of state law flows from the Supremacy Clause of the United States Constitution, which makes federal law "the

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[23] *Id.*
[24] *Quality Infusion Care, Inc. v. Health Care Service Corp.*, 628 F.3d 725, 728 (5th Cir. 2010).
[25] *Lindsey v. Sears Roebuck and Co.,* 16 F.3d 616, 618 (5th Cir.1994) (internal citations omitted).
[26] *Roberts v. Cardinal Servs.*, 266 F.3d 368, 373 (5th Cir.2001); *see also Feist v. Louisiana, Dept. of Justice, Office of the Atty. Gen.*, 730 F.3d 450, 452 (5th Cir. 2013) (court must view all facts and evidence in the light most favorable to the non-moving party).
[27] *Quorum Health Resources, L.L.C. v. Maverick County Hosp. Dist.*, 308 F.3d 451, 458 (5th Cir. 2002).
[28] *Patrick v. Ridge*, 394 F.3d 311, 315 (5th Cir. 2004) (alterations in original) (quoting *Celotex v. Catlett*, 477 U.S. 317, 322 (1986)).

supreme law of the land."[29] Under the Supremacy Clause, if there is a conflict between federal law and state law, the latter is "preempted" by federal law.[30] That is, federal law controls and the state law is set aside to the extent it conflicts with federal law.[31] Preemption may be either express or implied. State law is expressly preempted when "Congress expresses an explicit intent to preempt state law."[32] Where Congress has not explicitly displaced state law, federal law may nevertheless impliedly preempt state law where there is a clear congressional intent to preempt state or local law. Courts have identified at least three types of implied preemption: "field" preemption, "conflict" preemption, and "obstacle" preemption.[33] While Plaintiffs' arguments primarily rely on field and conflict preemption, some of their arguments can be construed as arguments for obstacle preemption. Accordingly, the Court will address all three grounds for preemption.

**1. Field Preemption**

Plaintiffs' preemption arguments rely heavily on field preemption. Field preemption arises where "[s]tates are precluded from regulating conduct in a field that Congress, acting within its proper authority, has determined must be regulated by its exclusive governance."[34] Congress may expressly provide that it intends to occupy a given field and that state regulation is therefore preempted with respect to that field.[35] When Congress has not expressly stated its intent to occupy a given field, field preemption may also "be inferred from a scheme of federal regulation so pervasive as to make reasonable the inference that Congress left no room for the States to

[29] U.S. CONST. art. VI, cl. 2.
[30] *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88. 108 (1992).
[31] *Id.*
[32] *Hetzel v. Bethlehem Steel Corp*., 50 F.3d 360, 363 (5th Cir. 1995).
[33] *Janvey v. Democratic Senatorial Campaign Comm., Inc*., 712 F.3d 185 (5th Cir. 2013). Some courts treat "obstacle" preemption as a form of "conflict" preemption.
[34] *Arizona v. United States*, 567 U.S. 387, 399 (2012).
[35] *United States v. Texas*, 97 F.4th 268, 278 (5th Cir. 2024)

supplement it."[36] However, "federal regulation . . . should not be deemed preemptive of state regulatory power in the absence of persuasive reasons either that the nature of the regulated subject matter permits no other conclusion, or that Congress has unmistakably so ordained."[37] Congress has not expressly preempted state regulatory powers with respect to the Section 340B program. Plaintiffs thus argue that field preemption should be inferred.[38]

The gravamen of Plaintiffs' field preemption arguments is that the nature of the Section 340B program is such that Congress left no room for Louisiana to exercise its regulatory powers with respect to contract pharmacies.[39] They argue that "Congress designed 340B to provide a comprehensive and exclusive plan for delivering a unique federal benefit—a substantial drug discount to specific, statutorily defined healthcare providers," and that "340B works through a carefully calibrated incentive structure."[40] They argue that, to achieve this "calibrated incentive structure," Congress "made 304B a closed system."[41] Presumably, Plaintiffs mean that Congress limited the program to the enumerated "covered entities," and precluded the distribution of Section 340B discounted drugs to ineligible healthcare providers or patients of ineligible providers.[42] Plaintiffs also point to HHS' "multi-faceted administrative enforcement scheme," which ensures that participants comply with the rules of the program and prevents the diversion of discounted

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[36] *English v. Gen. Elec. Co*., 496 U.S. 72, 79 (1990) (quoting *Rice v. Santa Fe Elevator Corp*., 331 U.S. 218, 230 (1947))

[37] *De Canas v. Bica*, 424 U.S. 351, 356 (1976) (quoting *Florida Lime & Avocado Growers v. Paul*, 373 U.S. 132, 142 (1963)).

[38] ECF No. 21-1 at 14, *Pharmaceutical Research and Manufacturers of America v. Liz Murrill*, Civ. No. 6:23-cv-997 (W.D. La. July 27, 2023); ECF No. 21-1 at 23-25, *AstraZeneca Pharmaceuticals LP v. Murrill*, Civ. No. 6:23-cv-1042 (W.D. La. Aug. 8, 2023); ECF No. 28-1 at 20-27, *AbbVie, et al. v. Murrill*, Civ. No. 6:23-cv-1307 (W.D. La. Sept. 21, 2023).

[39] *Id.*

[40] *Pharmaceutical Research and Manufacturers of America v. Liz Murrill*, Civ. No. 6:23-cv-997 (W.D. La. July 27, 2023) (ECF No. 21-1 at 14). Here, the Court quotes from the brief of Plaintiff Pharmaceutical Research and Manufacturers of America because that brief appears to contain most, if not all, of the arguments raised by the other Plaintiffs. The arguments in the *PRMA* brief also reflect the tenor of the arguments in the other Plaintiffs' briefs with respect to field preemption.

[41] *Id.* at 15.

[42] *Id.* at 14-15.

drugs to ineligible recipients.[43] Plaintiffs also note the interrelationship between the Section 340B program and the much larger federal Medicare and Medicaid programs and argue that this interrelationship requires uniformity because "[o]bligations under 340B, and violations of 340B, can have collateral consequences on these other federal programs."[44] Plaintiffs argue that Congress addressed this need for uniformity by making HHS the exclusive administrator of the Section 340B program and eliminating any role for the states: "Congress understandably chose to vest HHS and the federal courts—rather than 50 individual States—with the power to make carefully considered determinations regarding disputes, enforcement, and penalties."[45] Plaintiffs thus contend that "Act 358 invades the field *substantively* by purporting to define as a matter of state law the scope of manufacturers' 340B obligations," and invades "the federal field *procedurally* by creating its own scheme of oversight and enforcement."[46]

In *PhRMA v. McClain*,[47] the Eight Circuit recently affirmed the district court's ruling granting summary judgment and dismissing preemption claims involving an Arkansas statute similar to Act 358. Although *PhRMA* is not binding, the Court finds the reasoning of the district court and Eight Circuit in that case persuasive for the following reasons.

The statutory text governing the Section 340B program does not support the broad field preemption arguments made by Plaintiffs. The regulatory and enforcement framework outlined by Plaintiffs focuses on participating pharmaceutical companies and certain "covered entities" defined and delineated in the governing statutes and regulations.[48] Under the Section 340B program, pharmaceutical companies that wish to participate in the Medicare or Medicaid program

[43] *Id.* at 15.
[44] *Id.* at 17.
[45] *Id.*
[46] *Id.* at 18 (emphasis added).
[47] 95 F.4th 1136 (8th Cir. 2024).
[48] 42 U.S.C. §§ 256b, 1396r-8(a)(1), (5).

must enter into written agreements with HHS to provide discounted prices "for covered outpatient drugs purchased by a covered entity."[49] The "covered entities" are health care providers who generally provide services to low-income and rural patients.[50] As Plaintiffs correctly point out, the statute defines which health care providers qualify as "covered entities" eligible to receive discounted drugs under the Section 340B program.[51] The statute places restrictions on covered entities receiving the discounts to ensure that they do not receive duplicate discounts on drugs subject to a Medicare or Medicaid discount-sometimes referred to as "double dipping."[52] The statute also restricts "diversion" by providing that covered entities receiving discounted drugs can only provide them to their patients.[53] And Plaintiffs are correct that the federal statutory scheme imposes significant enforcement mechanisms to ensure compliance.[54]

However, Section 340B is silent with respect to the role of pharmacies who enter into contracts with covered entities to receive and dispense discounted drugs under Section 340B. The statute does not mention contract pharmacies in defining the health care providers qualified as "covered entities," nor does it refer to contract pharmacies in delineating the obligations of participating pharmaceutical companies with respect to covered entities.[55] Plaintiffs seem to suggest that Louisiana's Act 358 expands the federal statute's definition of "covered entities" to include contract pharmacies and, as a result, that it creates new substantive obligations on participating pharmaceutical companies to provide covered drugs directly to contract pharmacies

[49] 42 U.S.C. § 1396r-8(a); 42 C.F.R. Part 10 §§ 10.2, 10.3.
[50] *Astra USA, Inc. v. Santa Clara County, Cal.*, 563 U.S. 110, 115 (2011); 42 C.F.R. Part 10 §10.3.
[51] 42 U.S.C § 256b(a); *Astra USA*, 563 U.S. at 115.
[52] 42 U.S.C. § 256b(a)(5)(A)(i).
[53] 42 U.S.C. § 256b(a)(5)(B).
[54] *See, e.g.*, 42 U.S.C. § 256b(d); 42 C.F.R. §§ 10.10, 10.20 - 10.25.
[55] These requirements are sometimes referred to as the "purchase by" or "shall offer" requirements. *Sanofi Aventis U.S. LLC v. HHS*, 58 F.4th 696, 699-700 (3d Cir. 2023). Specifically, Section 340B requires participating pharmaceutical companies to provide discounts on covered drugs "purchased by" covered entities. *Id.* It also requires these companies to "offer each covered entity covered outpatient drugs" at a discount. *Id.*

without regard to the statutory and regulatory provisions governing the Section 340B program.[56] They also suggest that Act 358 essentially gives these pharmacies the same status as "covered entities" under the federal program.[57]

Plaintiffs, however, mischaracterize the relationship between covered entities and their contract pharmacies. In each case, discounted drugs under the program delivered to contract pharmacies are delivered *on behalf of* covered entities and subject to the contract between those entities and the pharmacies. When the pharmacies distribute those drugs, they distribute them on behalf of and for the benefit of a covered entity. Section 340B does not prevent covered entities from entering into contracts with independent pharmacies, but these contract pharmacies are not "covered entities" and nothing in Act 358 treats them as such.

The Fifth Circuit has cautioned that in applying the field preemption doctrine courts should define the relevant field "narrowly."[58] Here, Plaintiffs improperly frame the relevant field broadly to include the regulation of contract pharmacies on which the governing statute is silent. Accordingly, even if the 340B program constitutes an exclusive federal "field" with respect to the relationship between participating pharmaceutical companies and healthcare providers that qualify as "covered entities," the field does not extend to the relationship between contract pharmacies and covered entities and Act 358 does not, therefore, intrude on any exclusive federal regulatory scheme.

Moreover, as the courts point out in *PhRMA*, Plaintiffs' field preemption arguments also overstate the extent which the federal government "occupies" the field with respect to covered

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[56] *See, e.g.*, ECF No. 21-1 at 18, *PRMA* ("Notwithstanding the closed system, Act 358 nonetheless requires manufacturers to also 'offer' 340B-discounted drugs to contract pharmacies … expanding the scope of the federal obligation.") (citations omitted).
[57] *Id.*
[58] *United States v. Texas*, 97 F.4th at 278 (quoting *City of El Cenizo v. Texas*, 890 F.3d 164, 177 (5th Cir. 2018)) ("When analyzing field preemption, 'the relevant field should be defined narrowly.'").

health care providers and their contract pharmacies.[59] According to the Eighth Circuit, "the practice of pharmacy is an area traditionally left to state regulation" and "the federal government has 'traditionally regarded state law as a complementary form of drug regulation and has long maintained that state law offers an additional, and important, layer of consumer protection that complements [federal] regulation.'"[60] Given that Section 340B is silent on contract pharmacies that dispense Section 340B drugs under contract with covered entities, the Eighth Circuit was unwilling to dislodge the state from its traditional role in regulating pharmacies.[61]

Plaintiffs' reliance on the Third Circuit's decision in *Sanofi Aventis U.S. LLC (Sanofi) v. U.S. Dep't of Health and Human Services* to support their field preemption claim is misplaced.[62] Plaintiffs argue that *Sanofi* essentially creates a federal right under Section 340B allowing participating pharmaceutical companies to restrict the delivery of discounted drugs to contract pharmacies.[63] According to Plaintiffs, Louisiana's Act 358 intrudes on this right by preventing pharmaceutical companies who participate in the Federal program from restricting deliveries of discounted drugs under Section 340B to contract pharmacies.[64] They also argue that *Sanofi* holds that the statutory silence on contract pharmacies precludes the state from "supplementing" Section 340B by adopting regulations on contract pharmacies.[65]

The Court disagrees on both counts. In *Sanofi*, the plaintiff challenged a regulation promulgated by the Department of Health and Human Services requiring pharmaceutical companies participating in the Section 340B program to provide 340B discounted drugs to an

[59] 95 F.4th at 1143.
[60] *Id.* (cleaned up).
[61] *Id.* at 1144.
[62] 58 F.4th 696 (3d Cir. 2023).
[63] ECF No. 28-1 at 14-16, *AbbVie*; ECF No. 21-1 at 22-23, *PRMA*; ECF No. 21-1 at 23-24, *AstraZeneca Pharmaceuticals*.
[64] *Id.*
[65] *Id.*

unlimited number of private pharmacies under contract with "covered entities" eligible to receive the discounted drugs.[66] Prior to the implementation of the regulation, pharmaceutical companies participating in the Section 340B program had imposed policies and restrictions on covered entities receiving discounted drugs.[67] These policies generally provided that participating pharmaceutical companies would deliver Section 340B discounted drugs to only one outside contract pharmacy for each covered entity.[68] Participating pharmaceutical companies implemented these policies in response to a proliferation of outside pharmacies that entered into contracts with covered entities eligible to receive discounted drugs.[69] In response, HHS took the position that Section 340B precludes participating pharmaceutical companies from limiting the number of contract pharmacies eligible to receive discounted drugs under the program.[70] The district court rejected HHS' reading of the statute, noting that the statute "never mentions pharmacies, which is a 'strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies.'"[71] The district court then entered a permanent injunction enjoining HHS from implementing the new regulation prohibiting participating pharmaceutical companies from restricting contract pharmacies.

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[66] 58 F.4th at 701-703.
[67] *Id.* at 700-701.
[68] *Id.*
[69] *Id.*
[70] *Id.* at 701-701.
[71] *AstraZeneca Pharms. LP v. Becerra ("Becerra II")*, No. CV 21-27-LPS, 2022 WL 484587, at *6 (D. Del. Feb. 16, 2022) (quoting *AstraZeneca Pharms. LP v. Becerra ("Becerra I")*, 543 F. Supp. 3d 47, 59 (D. Del. 2021). In *Becera I*, the same district court again noted the limited scope of the Section 340B program:

> The statute is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs. Pharmacies are not mentioned anywhere in the statutory text – neither in § 256b(a)(1), which (as both parties agree) contains the relevant command, nor in § 256b(a)(4), which provides the definition of "covered entity." When a statute does not include even a single reference to the pertinent word (e.g., "pharmacy"), it is highly unlikely (if not impossible) that the statute conveys a single, clear, and unambiguous directive with respect to that word. ***Here, the absence of any reference to "pharmacies" is a strong indication that the statute does not compel any particular outcome with respect to covered entities' use of pharmacies.***

543 F. Supp. 3d at 59 (emphasis added).

In affirming the district court's permanent injunction, the Third Circuit agreed that the text of the statute does not require "delivery to an unlimited number of contract pharmacies."[72] Like the district court, the Third Circuit noted that "nowhere does section 340B mention contract pharmacies."[73] The court reasoned that section 340B does not address the contractual relationship between covered entities and their contract pharmacies or how discounted drugs are delivered or distributed as long as the drugs are "purchased by" or "offered to" a "covered entity" and the covered entity complies with the program's restrictions on "double dipping" and diversion.[74] Accordingly, the court held that HHS did not have the statutory authority under section 340B to prevent participating pharmaceutical companies from placing restrictions on their deliveries of discounted drugs to contract pharmacies.[75]

Plaintiffs not only misread the scope of *Sanofi*'s holding, but the holding also directly undercuts Plaintiffs' field preemption argument. *Sanofi* addresses only the limited question of HHS' statutory authority to implement a regulation regarding the use of contract pharmacies by covered entities. The courts in *Sanofi* held that HHS lacked statutory authority to regulate contract pharmacies in connection with the Section 340B program because the "statute is silent as to the role that contract pharmacies may play in connection with covered entities' purchases of 340B drugs."[76] The fact that HHS lacks authority to regulate contract pharmacies under Section 340B does not, however, mean that the statute affirmatively precludes state regulation pertaining to contract pharmacies or otherwise "occupies the field."[77] If, as the courts in *Sanofi* hold, Section 340B "does not compel any particular outcome with respect to covered entities' use of

[72] *Sanofi*, 58 F.4th at 704.
[73] *Id.* at 703.
[74] *Id.* at 704.
[75] *Id.*
[76] *Becera I*, 543 F. Supp. 3d at 59.
[77] *Id.* ("the statute does not compel any particular outcome with respect to covered entities' use of pharmacies.").

pharmacies," Plaintiffs cannot maintain a field preemption claim on the grounds that "Congress has unmistakably so ordained" that Section 340B displaces state law regulations on contract pharmacies.[78]

Plaintiffs "procedural invasion" argument for field preemption similarly fails. Plaintiffs contend that Louisiana's Act 358 intrudes on the enforcement scheme adopted by HHS to police the Section 340B program. They argue that this enforcement scheme is exclusive and, citing the Supreme Court's decision in *Astra USA, Inc. v. Santa Clara Cnty., Cal.*,[79] argue that "no gap exists and federal authority is exclusive" with respect to enforcement of the parties' rights and obligations under the Section 340B program.[80]

As with *Sanofi*, Plaintiffs misread the Supreme Court's holding in *Astra*. In *Astra*, Santa Clara County sued pharmaceutical companies participating in the Section 340B program for overcharges on covered drugs.[81] The county operated covered entities eligible to participate in the program and alleged that the participating pharmaceutical companies breached the agreements that they entered into with HHS to provide discounted drugs.[82] The Court held that HHS' enforcement mechanism was the exclusive means for policing the pricing requirements of Section 340B and that the statute precluded a private right of action by covered entities seeking to enforce the terms of the agreements between HHS and participating pharmaceutical companies.[83] The Court did not, however, address the role of contract pharmacies—its ruling pertains solely to participating pharmaceutical companies, covered entities, and their compliance with the pricing requirements of the Section 340B program.

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[78] *De Canas*, 424 U.S. at 356 (quoting *Florida Lime & Avocado Growers v. Paul*, 373 U.S. 132, 142 (1963)).
[79] 563 U.S. 110 (2011).
[80] ECF No. 21-1 at 19.
[81] 563 U.S. at 116.
[82] *Id.*
[83] *Id.* at 118-120.

Turning to the text of Act 358, the Louisiana statute creates an enforcement mechanism, but that mechanism pertains solely to pharmaceutical companies' actions toward pharmacies who enter into contracts with covered entities under the Section 340B program.[84] The Louisiana statute does not address the pharmaceutical companies' agreements with HHS or the pricing, diversion, or "double dipping" restrictions addressed in the HHS' enforcement scheme. Accordingly, even if the federal statute "occupies the field" with respect to the enforcement of the Section 340B program, Louisiana's Act 358 does not encroach on that enforcement scheme.

Finally, the Court turns to Plaintiffs' argument based on the interrelationship between the Section 340B program and the Medicaid and Medicare programs. Plaintiffs argue that this interrelationship requires uniformity and precludes states from regulating contract pharmacies.[85] Again, the Court disagrees. As explained above, Section 340B is silent with respect to contract pharmacies, and Plaintiffs have not pointed to any provisions in the statutes governing the Medicare or Medicaid programs that address pharmacies who enter into contracts with covered entities under Section 340B. Accordingly, it is unclear to the Court how the interrelationship between Section 340B and the Medicare and Medicaid programs requires uniformity with respect to contract pharmacies when none of these statutes address contract pharmacies.

In sum, the Court concludes that Plaintiffs cannot establish that "Congress has unmistakably so ordained" that state regulatory power be displaced with respect to contract pharmacies under the Section 340B program. Plaintiffs' field preemption claim therefore fails.

[84] La. R.S. 40:2885.
[85] *See, e.g.*, ECF No. 21-1 at 17.

**2. Conflict Preemption Based on *Sanofi.***

The Court now turns to Plaintiffs' "conflict" preemption claim.[86] "Conflict" preemption applies "where complying with both federal law and state law is impossible…."[87] In arguing conflict preemption, Plaintiffs re-urge many of the same arguments they urge with respect to field preemption: that Act 358 conflicts with the balance of incentives created by the Section 340B program, imposes additional obligations on pharmaceutical companies that conflict with their obligations under the federal statute, and conflicts with HHS' enforcement scheme. For the same reasons explained above with respect to field preemption, these arguments do not support conflict preemption. The statute governing the Section 340B program does not address contract pharmacies, which are the subject matter of Louisiana's Act 358. Therefore, Louisiana's contract pharmacy regulations cannot, by definition, *conflict* with Section 340B. Plaintiffs also, again, rely heavily on *Sanofi* to support their conflict preemption claim.[88] But, as with Plaintiffs' field preemption claim, *Sanofi*'*s* holding is fatal to Plaintiffs' conflict preemption claim. Specifically, if Section 340B does not address contract pharmacies or the relationship between covered entities and their contract pharmacies, a state statute that specifically addresses contract pharmacies cannot conflict with Section 340B. Put another way, Plaintiffs cannot credibly argue that it is impossible to comply with both Louisiana Act 358 and the federal Section 340B program in light of *Sanofi*.

Plaintiff AstraZeneca Pharmaceuticals also argues that conflict preemption applies because Louisiana Act 358 is "a price regulation that conflicts with, and is preempted by, the federal patent law."[89] In that regard, Plaintiffs cite *Biotechnology Indus. Org. ("BIO") v. District of Columbia*.[90]

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[86] In *PhRMA*, the Eighth Circuit also rejected the plaintiff's "conflict" and "obstacle" preemption claims. For the reasons that follow, the Court finds the Eighth Circuit's reasoning persuasive.
[87] *Janvey v. Democratic Senatorial Campaign Comm., Inc*., 712 F.3d 185, 200 (5th Cir. 2013).
[88] ECF No. 21-1 at 13, *AstraZeneca Pharmaceuticals*.
[89] ECF No. 21-1 at 16, *AstraZeneca Pharmaceuticals*; ECF No. 228-1.
[90] 496 F.3d 1362 (Fed. Cir. 2007).

The *BIO* case does not support AstraZeneca's conflict preemption argument based on federal patent law. In *BIO*, the District of Columbia City Council adopted legislation prohibiting "any patented drug from being sold in the district for an excessive price."[91] The Federal Circuit first observed that one of the objectives of the Patent Clause of the Constitution as well as federal patent statutory protections is to balance the tension between two objectives: "to reward innovators with higher profits and to keep prices reasonable for consumers."[92] The court held that the District of Columbia price statute expressly targeted the price of patented drugs and thus falls directly "within the scope of the patent laws, and its effect is to shift the benefits of a patented innovation from inventors to consumers."[93] Accordingly, the District of Columbia statute "re-balance[s] the statutory framework of rewards and incentives insofar as it relates to inventive new drugs."[94] The Federal Circuit concluded that the D.C. Council's efforts in this regard conflicted with "the goals established by Congress in the patent laws" because the D.C. Council's legislation was expressly "targeted at the patent right" and "applies only to patented drugs."[95]

Here, unlike the D.C. Council's legislation, Louisiana's Act 358 does not, on its face, target patent rights or, by its terms, apply only to patented drugs or the price of patented drugs. As a condition of participating in Medicare and Medicaid, participating pharmaceutical companies agree to provide discounted drugs in the Section 340B program. These discounts are set by the federal government, not the State of Louisiana or Act 358.[96] Act 358, addresses only contract pharmacies, a matter that is not addressed in Section 340B. Accordingly, *BIO* does not support Plaintiffs' conflict preemption claims.

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[91] *Id*. at 1364.
[92] *Id*. at 1372.
[93] *Id*. at 1373.
[94] *Id*. at 1374.
[95] *Id*.
[96] 42 U.S.C. § 256b(a)(1); 42 C.F.R. Part 10 § 10.10.

### 3. Obstacle Preemption

Finally, the Court turns to Plaintiffs' "obstacle" preemption claims. "Obstacle" preemption occurs where "state law creates an unacceptable obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[97] As with their conflict preemption arguments, Plaintiffs' re-urge most of the same arguments urged with respect to their field preemption claims, namely that Act 358 conflicts with the balance of incentives created by the Section 340B program, imposes additional obligations on pharmaceutical companies that conflict with their obligations under the federal statute, and conflicts with HHS' enforcement scheme. For the reasons discussed above, Act 358's provisions addressing contract pharmacies do not create "an unacceptable obstacle to the accomplishment and execution" of Congress' objectives reflected in Section 340B because Section 340B does address contract pharmacies. Moreover, Act 358 arguably *advances* Congress' objectives with respect to the Section 340B program. In *Sanofi*, the Third Circuit noted the objectives of the Section 340B program:

> "[C]overed entities," typically care for low-income and rural persons. Section 340B helps providers do that. First, it gives them ***extra revenue from serving insured patients***: they turn a profit when insurance companies reimburse them at full price for drugs that they bought at the 340B discount. Second, ***it enables them to give uninsured patients drugs at little or no cost***.[98]

Louisiana's Act 358 arguably advances these objectives by allowing covered entities who do not operate in-house pharmacies to contract with multiple pharmacies and thus increase their revenues from insured patients who use those pharmacies. Multiple contract pharmacies also arguably provide wider coverage for patients of covered entities.

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[97] *Janvey,* 712 F.3d at 200.
[98] *Sanofi*, 58 F.4th at 699.

In sum, Plaintiffs' "obstacle" preemption challenge to Act 358 similarly fails. The Court grants the Defendants' Motions for Summary Judgment with respect to Plaintiffs' preemption claims.

**C. Vagueness.**

The Court next addresses the claims by Plaintiffs PRMA and AbbVie that Act 358 is unconstitutionally vague and, therefore, violates the Due Process Clause of the Fourteenth Amendment.[99] A law is unconstitutionally vague when it: "(1) fails to apprise persons of ordinary intelligence of the prohibited conduct, or (2) encourages arbitrary and discriminatory enforcement."[100] Mere imprecision does not render a statute vague.[101] In fact, "[a] facial challenge for vagueness is appropriate only on an allegation that the law is vague not in the sense that it requires a person to conform his conduct to an imprecise but comprehensible normative standard, but rather in the sense that no standard of conduct is specified at all."[102]

PRMA's and AbbVie's vagueness challenge centers on the use of the term "interfere" in Act 358. Part A of the statute states that a pharmaceutical manufacturer or distributor "shall not deny, restrict, prohibit, or *otherwise interfere* with, either directly or indirectly, the acquisition of a 340B drug by, or delivery of a 340B drug to, a pharmacy that is under contract with a 340B entity …."[103] Part B of the statute simply provides that the manufacturer or distributor "shall not *interfere* with a pharmacy contracted with a 340B entity."[104] According to Plaintiffs, the statute "gives no indication of what conduct will be called 'interference' with 'the acquisition of a 340B drug' under a contract-pharmacy arrangement."[105] As a result, they argue that the statute fails to provide them

[99] U.S. CONST. Amend. XIV, § 1.
[100] *City of Chicago v. Morales*, 527 U.S. 41, 90 (1999).
[101] *Ferguson v. Estelle*, 718 F.2d 730, 735 (5th Cir. 1983).
[102] *Id*. (quoting *Coates v. Cincinnati*, 402 U.S. 611, 614 (1971)).
[103] La. R.S. 40:2884(A).
[104] La. R.S. 40:2884(B).
[105] ECF No. 28-1 at 44.

with reasonable notice whether their "conduct is prohibited and is so indefinite that it authorizes the Attorney General to engage in arbitrary and discriminatory enforcement."[106] Plaintiffs argue that Act 358's "geographic scope is also vague" in that it "applies to any 'pharmacy' in the entire United States where 'drugs are dispensed and pharmacy primary care is provided to residents of [Louisiana].'"[107]

Act 358 does not define the term "interfere." But the state argues that the statutory context of the term "interfere" in Part A of Act 358 gives the term a definite meaning sufficient to overcome a vagueness challenge. The Court agrees. The state's argument relies on the *"noscitur a sociis"* canon of statutory construction.[108] That canon is alternatively referred to as the "associated-words canon" and provides that "[w]hen several nouns or verbs or adjectives or adverbs—any words—are associated in a context suggesting that the words have something in common, they should be assigned a permissible meaning that makes them similar."[109] In Act 358, the term "interfere" is used in the context of the statutory prohibition to "deny, restrict, prohibit, or *otherwise* interfere" with the acquisition or delivery of a Section 340B drug to a contract pharmacy.[110] All of the preceding words in this list involve actions designed to prevent or hinder the acquisition or delivery of these discounted drugs to contract pharmacies designated by covered entities. Accordingly, the term "interfere" as used in Act 358 should be construed as proscribing actions that prevent or hinder the acquisition or delivery of Section 340B drugs to contract pharmacies. This is consistent with one of the dictionary definitions of the term: "to be or create a hindrance or obstacle."[111] It is also consistent with the introductory title of the statute: "Prohibition of certain discriminatory

[106] *Id*. at 43.
[107] *Id.* At 46.
[108] ECF No. 49-4 at 25.
[109] SCALIA & GARNER, READING LAW 195 (2012)
[110] La. R.S. 40:2884(A).
[111] "Interfere," *American Heritage Dictionary* (2022), https://www.ahdictionary.com/word/search.html?q=interfere (accessed Sept. 23, 2024).

actions by a manufacturer or distributor related to 340B entities."[112] Considering the definition of "interfere" and its textual context in Act 358, the term is sufficiently definite to provide notice of the conduct proscribed and to prevent arbitrary or discriminatory enforcement, at least with respect to Part A.

Part B of Act 358 does not have the textual clues of Part A with respect to the scope of the term "interfere"—it simply states that a pharmaceutical company "shall not interfere" with a contract pharmacy.[113] However, nothing in the statute suggests that the term "interfere" in part B should be given a meaning different from that in Part A. Part A and Part B should be construed consistently to proscribe conduct that prevents or hinders the delivery of Section 340B drugs to pharmacies under contract with covered entities eligible to receive the drugs. As with the use of the term in Part A, this reading of the term "interfere" is consistent with the dictionary definition of the term and the title of the statute, which covers both Part A and Part B of La. R.S. 40:2884.

Moreover, Plaintiffs' reliance on *Carolina Youth Action Project ("CYAP"), et al. v. Wilson* to argue that Act 358 use of the term "interfere" is unconstitutionally vague is misplaced.[114] The plaintiffs in *CYAP* challenged a state statute that made it a crime to "willfully or unnecessarily" "interfere with or to disturb in any way or in any place the students or teachers of any school or college in this State," "to loiter about such school or college premises," or "to act in an obnoxious manner thereon."[115] The court noted that, in assessing a constitutional vagueness challenge "[t]he degree of vagueness tolerated ... depends in part on the type of statute."[116] Because "the 'consequences of imprecision are qualitatively less severe,'" "[l]ess clarity is required in purely

[112] La. R.S. 40:2884.
[113] La. R.S. 40:2884(B).
[114] 60 F.4th 770, 786 (4th Cir. 2023).
[115] *Id.*
[116] *Id.* at 781 (quoting *Manning v. Caldwell for City of Roanoke*, 930 F.3d 264, 272 (4th Cir. 2019)).

civil statutes," while "laws imposing 'criminal penalties' or 'threaten[ing] to inhibit the exercise of constitutionally protected rights' are subject to 'a stricter standard.'"[117] The court concluded that, given the disjunctive text of the statute, the statute failed to "explain the law's scope" or limit the discretion of prosecutors, and thus posed the danger of sweeping in protected speech.[118]

Act 358 does not pose the same danger to constitutionally protected activities as the statute at issue in *CYAP*. Act 358 is enforceable through civil penalties and injunctive relief under Louisiana's Unfair Trade Practices and Consumer Protection Law and thus does not invoke criminal penalties in contrast to the law at issue in *CYAP*.[119] Moreover, as explained above, Act 358 provides sufficient textual context for the term "interfere" to allow Plaintiffs to determine the scope of the law and to limit the discretion of the state in enforcing the statute. Moreover, the law at issue in the other case implicated significant First Amendment concerns given how the term "interfere" or "interference" was used in the statute. Here, Plaintiffs suggest that Act 358 may similarly infringe protected speech. But the statutory context of the term "interfere" limits its application to unprotected, non-expressive conduct aimed at preventing or hindering contract pharmacies from acquiring or receiving Section 340B drugs on behalf of covered entities.

Finally, Plaintiffs argue that Act 358 is "geographically" vague in the sense that it is not limited to contract pharmacies in the State of Louisiana, but instead broadly applies to any pharmacy in the United States that serves patients in Louisiana. The Court disagrees. Act 358 is specifically limited to pharmacies under contract with a covered entity in Louisiana—in other words, a Louisiana healthcare provider—and that provider's Louisiana-based patients. It is unclear to the Court how this provision renders the statute "geographically" vague given that the statute

[117] *Id.* (quoting *Manning*, 930 F.3d at 272)
[118] *Id.* (quoting *Manning*, 930 F.3d at 272)
[119] La. R.S. 40:2885.

turns on the existence of a contractual relationship between the pharmacy—whether in-state or out-of-state—and a Louisiana healthcare provider. The limitation of the statute to pharmacies that have a contractual relationship with a covered entity in Louisiana provides some boundaries and limitations on the scope of the Act 358.

In sum, Plaintiffs' constitutional vagueness arguments fail as a matter of law. Accordingly, the Court grants the Defendants' Motions for Summary Judgment with respect to these claims.

**D. Contracts Clause.**

The Contracts Clause prohibits States from passing laws "impairing the Obligation of Contracts."[120] The Supreme Court's current two-step analysis for Contracts Clause challenges requires that a court first determine whether the state law at issue substantially impairs a contractual relationship, and if so, whether it does so for a legitimate purpose.[121] The Fifth Circuit, relying on the last Supreme Court case to strike down a state law on the basis of a Contracts Clause violation,[122] has adopted basically the same test, albeit in three steps: (1) the court must determine whether the state law has in fact operated as a substantial impairment of a contractual relationship; (2) if it does, the court must consider the justification offered by the state for that impairment, which must be significant and legitimate; and (3) if the state offers a legitimate justification for the impairment, the court must determine whether the impairment is reasonable and necessary.[123]

Under the Section 340B Program, private prescription drug companies, as a condition of having their outpatient drugs covered through Medicaid and Medicare Part B, are required to enter a pharmaceutical pricing agreement ("PPA") with the HHS Secretary under which they agree to

[120] U.S. CONST. art. I, § 10.
[121] *Sven v. Melin*, 138 S. Ct. 1815, 1822 (2018).
[122] *Allied Structural Steel Co. v. Spannaus*, 438 U.S. 234 (1978).
[123] *United Healthcare Ins. Co. v. Davis*, 602 F.3d 618, 630 (5th Cir. 2010); *Lipscomb v. Columbus Mun. Separate Sch. Dist.*, 269 F.3d 494, 504–05 (5th Cir. 2001).

offer Section 340B providers outpatient drugs at or below an applicable discounted and statutorily determined price referred to as the "ceiling price."[124] The terms of a PPA effectively mirror the statute. In fact, the Supreme Court has held that "the PPAs simply incorporate statutory obligations and record the manufacturers' agreement to abide by them. The form agreements, composed by HHS, contain no negotiable terms . . . . [Thus,] the 340B Program agreements serve [merely] as the means by which drug manufacturers opt into the statutory scheme."[125]

Plaintiff AstraZeneca alleges that Act 358 expands the list of covered entities and is therefore an "expansion of beneficiaries."[126] But Act 358 does not change or expand which entities qualify as 340B "covered entities." Thus, it does not expand or otherwise enlarge the beneficiaries of the Section 340B program. Nor does Act 358 change what prices drug companies may charge covered entities—Act 358 only affects the *delivery* or *acquisition* of Section 340B drugs. As a result, AstraZeneca cannot point to any way in which the Act expands or contradicts its PPA because, like the statute, the PPA is silent as to delivery to or acquisition of Section 340B drugs to contract pharmacies.

The cases on which AstraZeneca predicates its Contracts Clause claim are easily distinguishable. In *Allied Structural v. Spannaus*, the Supreme Court struck down a Minnesota law that required a company to provide additional pension benefits after it had agreed to provide such benefits under specific contractual provisions.[127] Unlike the Act, the Minnesota law in that case effectively changed the terms of the contract. Here, the terms of the PPA remain unchanged. Similarly, in *United Healthcare Ins. Co. v. Davis,* the Fifth Circuit held that the Contracts Clause prohibited Louisiana from enacting legislation increasing obligations on companies that had

[124] See 42 U.S.C. § 256b(a)(1).
[125] *Astra USA, Inc. v. Santa Clara County*, 563 U.S. 110, 118 (2011).
[126] See Complaint, ECF No. 1, at ¶¶ 78-79.
[127] 438 U.S. at 245–46.

agreed to insure state employees under specific conditions.[128] Nothing that Louisiana has done in Act 358 increases or in any way changes AstraZeneca's obligations under its PPA. Finally, in *Lipscomb v. Columbus Municipal Separate School District*, the Fifth Circuit determined that the voiding of longstanding land leases violated the Contacts Clause.[129] Act 358, in contrast, does not void any contracts.

Even if the Court were to find that Act 358 somehow impairs AstraZeneca's PPA by preventing restrictions on contract pharmacies, the State would have a legitimate purpose for doing so. The Supreme Court has "repeatedly held that unless the State is itself a contracting party, courts should 'properly defer to legislative judgment as to the necessity and reasonableness of a particular measure.'"[130] The Fifth Circuit has also stated that "[u]nder modern caselaw, states have some leeway to alter parties' contractual relationships 'to safeguard the vital interests of [their] people.'"[131] The Fifth Circuit has also observed that "remedying . . . a broad and general social or economic problem qualifies as a significant and legitimate public purpose."[132] As the Eighth Circuit noted in *PhRMA*, the practice of pharmacy is an area traditionally left to state regulation" and "the federal government has 'traditionally regarded state law as a complementary form of drug regulation and has long maintained that state law offers an additional, and important, layer of consumer protection that complements [federal] regulation.'"[133] The state could credibly argue that Act 358 promotes greater access to discounted drugs by preventing restrictions on the distribution of those drugs through multiple contract pharmacies.

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[128] 602 F.3d at 630.
[129] 269 F.3d at 514.
[130] *Keystone Bituminous Coal Ass'n v. DeBenedictis*, 480 U.S. 470, 505 (1987) (quoting *Energy Reserves Grp., Inc. v. Kan. Power & Light Co*., 459 U.S. 400, 413 (1983) (citations omitted)).
[131] *Next Era Cap. Holdings, Inc. v. Lake*, 48 F.4th 306, 328 (5th Cir. 2022) (quoting Energy Reserves Grp., 459 U.S. at 410).
[132] *Jones v. La. Bd. of Supervisors of Univ. of La. Sys*., 809 F.3d 231, 242 (5th Cir. 2015).
[133] *Id.* (cleaned up).

The Fifth Circuit also recently observed that "the Contracts Clause is not what it once was."[134] One of the principles that "sapped the Contracts Clause of its earlier force" is applicable in the present case, namely the expectation that contracting parties must recognize that regulation is possible, which rings "especially true in highly regulated industries."[135] The drug industry is a "pervasively regulated business."[136] Since AstraZeneca can reasonably expect regulation with respect to the sale of drugs and, especially with respect to its voluntary participation in federal benefit programs such as Medicaid and Medicare, its claim "fails at the threshold question for proving a modern Contracts Clause violation."[137]

**E. Takings Clause.**

The Takings Clause of the Fifth Amendment to the Constitution, which is "applicable to the States through the Fourteenth Amendment,"[138] provides: "[N]or shall private property be taken for public use, without just compensation."[139] Takings claims are recognized as to both personal property, including goods, and real property.[140] A taking can be either *per se* or regulatory, both of which entitle the property owner to just compensation.[141] A *per se* taking occurs "[w]hen the government physically acquires private property for a public use," including "when the government physically takes possession of property without acquiring title to it."[142]

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[134] *NextEra Energy Cap. Holdings, Inc.,* 48 F.4th at 328.
[135] *Id*.
[136] *United States v. Schiffman*, 572 F.2d 1137, 1142 (5th Cir. 1978).
[137] *NextEra Energy Cap. Holdings, Inc.,* 48 F.4th at 328; *see also United Healthcare Ins. Co. v. Davis,* 602 F.3d 618, 627-28 (5th Cir. 2010).
[138] *Cedar Point Nursey v. Hassid*, 594 U.S. 139, 147 (2021).
[139] U.S. Const. Amend. V.
[140] *Horne v. Dep't of Agriculture*, 576 U.S. 350, 358 (2015).
[141] *Cedar Point Nursey*, 594 U.S. at 147–49.
[142] *Id*. at 147.

A taking can also occur as a result of "the deprivation of the former owner rather than the accretion of a right or interest to the sovereign."[143] The Supreme Court has held that a regulatory taking occurs when a regulation "goes too far" in limiting an owner's use of her property.[144]

In order to determine whether a regulation amounts to a taking, courts apply the test developed in *Penn Central Transportation Company v. City of New York*.[145] The *Penn Central* test requires "balancing factors such as the economic impact of the regulation, its interference with reasonable investment-backed expectations, and the character of the government action."[146] A regulation that deprives a property owner of "all economically beneficial uses" of her property constitutes a regulatory taking.[147]

Regardless of whether the government pays just compensation for a taking, property may only "be taken for public use."[148] The Supreme Court has held that the phrase "public use" requires that the taking "serve[ ] a 'public purpose.'"[149] The Court has "defined that concept broadly, reflecting [the Court's] longstanding policy of deference to legislative judgments" in redevelopment of property, and in "a purely economic context" as well.[150]

The Fifth Circuit has held that when private parties "voluntarily accept responsibilities under" federal law because "they consider it in their best interest to do so," no taking occurs.[151] Under this principle, "[g]overnmental regulation that affects a group's property interests does not

[143] *Ruckelshaus v. Monsanto Co*., 467 U.S. 986, 1005–06 (1984) (internal quotation marks and citation omitted).
[144] *Pennsylvania Coal Co. v. Mahon*, 260 U.S. 393, 415 (1922).
[145] 438 U.S. 104 (1978).
[146] *Id*.
[147] *Lucas v. South Carolina Coastal Council*, 505 U.S. 1003, 1019–20 (1992) (emphasis in original) (finding a regulatory taking, and thus requiring just compensation, when enforcement of a "coastal-zone construction ban" rendered beachfront property "valueless").
[148] U.S. Const. Amend. V.
[149] *Kelo v. New London,* 545 U.S. 469, 480 (2005).
[150] *Id*. at 480–82 (citing Berman v. Parker, 348 U.S. 26 (1954), *Hawaii Hous. Auth. v. Midkiff*, 467 U.S. 229 (1984), and *Monsanto*, 467 U.S. at 1014).
[151] *Burditt v. U.S. Dep't of Health & Hum. Servs.,* 934 F.2d 1362, 1376 (5th Cir. 1991).

constitute a taking of property where the regulated group is not required to participate in the regulated industry."[152] In *Burditt*, the Fifth Circuit held that a "state law limiting fees that nursing homes voluntarily participating in Medicaid may charge non-Medicaid patients effects no taking '[d]espite the strong financial inducement to participate in Medicaid.'"[153]

The Supreme Court has also applied the *Penn Central* test to determine whether a voluntary exchange with the federal government constituted a taking. In *Monsanto*, the Supreme Court rejected in part a takings challenge to the 1978 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 61 Stat. 163, as amended, 7 U.S.C. § 136, *et seq*. 467 U.S. at 1006–08.[154] The 1978 amendments to FIFRA allowed the Environmental Protection Agency ("EPA") to disclose trade secrets contained in applications for licenses to sell pesticides ten years after the applicant filed its application. The Court rejected the takings claim to the extent an applicant was "aware of the conditions under which the data [were] submitted" because "a voluntary submission of data by an applicant in exchange for the economic advantages of a registration can hardly be called a taking."[155] *Monsanto* framed the issue under the *Penn Central* test.[156] After considering the *Penn Central* factors, the Court focused on the third factor: the statute's "interference with reasonable investment-backed expectations."[157] As to submissions of applications after 1978—meaning, those submitted with knowledge of the potential for disclosure of trade secrets contained therein—"the force of [the third] factor [was] so overwhelming" as to

[152] *Id*. (internal quotation marks and citations omitted).
[153] *Id*. (quoting parenthetically *Minnesota Ass'n of Health Care Facilities, Inc. v. Minnesota Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984), cert. denied, 469 U.S. 1215 (1985)).
[154] 467 U.S. at 1014
[155] *Id*.
[156] *See id*. at 1005–06.
[157] *Id*. (quoting *PruneYard Shopping Ctr. v. Robins*, 447 U.S. 74, 83 (1980)).

be dispositive.[158] The Court further concluded that "the conditions [were] rationally related to a legitimate Government interest" in regulating pesticides.[159]

The Court disagrees with Plaintiffs' characterization of Act 358 as compelling direct, confiscatory sales to private pharmacies. Discounted drugs are sold to *covered entities* under the terms and conditions of the PPAs and the Section 340B program—they are not sold to pharmacies that enter into contracts to dispense the drugs on behalf of covered entities. Act 358 only prevents pharmaceutical companies from restricting the ability of covered entities to contract with multiple pharmacies to dispense Section 340B drugs to their patients. Because Act 358 does not compel Plaintiffs to directly sell 340B drugs to pharmacies, it is not a taking for purposes of the Takings Clause.

In *Eli Lilly*,[160] the court rejected the argument AbbVie asserts here that an unconstitutional private taking occurs when the government requires that a drug company transfer its drugs to contract pharmacies as a condition of obtaining coverage of its drugs under federal health insurance programs. The court there reasoned that the plaintiff's voluntary participation in these programs "foreclosed the possibility that the statute could result in an imposed taking of private property."[161] The Court finds this reasoning persuasive. Act 358 does not compel drug manufacturers to transfer Section 340B discounted drugs either to the government or to a private party. The statute only applies to drug manufacturers who voluntarily participate in the Medicaid and Medicare programs. AbbVie is not compelled to participate in these programs.

Furthermore, consideration of the *Penn Central* factors suggest that Act 358 is not so onerous as to constitute a regulatory taking. The history of the Section 340B program and litigation

[158] *Id*.
[159] *Id*. at 1007.
[160] 2021 WL 5039566 (S.D. Ind. 2021).
[161] *Id*.

surrounding it suggests that regulations requiring delivery and forbidding restrictions against delivery to contract pharmacies were foreseeable. In *Penn Central*,[162] the Supreme Court recognized that a taking is less readily found in a case where the governmental interference with property arises from a public program that adjusts to benefits and burdens of economic life to promote public welfare. This character of regulation stands in contrast to a physical invasion of property by the government. The character of the regulations at issue resembles the former and not the latter.

In sum, AbbVie cannot succeed on its takings claim. The Court, therefore, grants Defendants' Motions for Summary Judgment with respect to this claim.

## III.
## CONCLUSION

For the foregoing reasons, the Court rules as follows:

(1) PRMA's Motion for Summary Judgment in Case No. 6:23-cv-997 [ECF No. 21] is DENIED;

(2) The Cross Motions for Summary Judgment filed by the State of Louisiana [ECF No. 41] and the Louisiana Primary Care Association [ECF No. 44] in Case No. 6:23-cv-997 are GRANTED; all claims asserted in Case No. 6:23-cv-997 are DISMISSED;

(3) AstraZeneca's Motion for Summary Judgment in Case No. 6:23-cv-1042 [ECF No. 21] is DENIED;

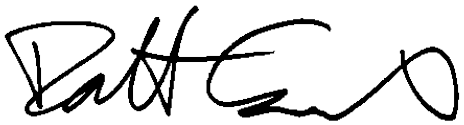
(4) The Cross Motions for Summary Judgment filed by the State of Louisiana [ECF No. 43] and the Louisiana Primary Care Association [ECF No. 45] in Case No. 6:23-cv-1042 are GRANTED; all claims asserted in Case No. 6:23-cv-1042 are DISMISSED;

[162] 438 U.S. 104 (1978).

(5) AbbVie's Motion for Summary Judgment in Case No. 6:23-cv-1307 [ECF No. 28] is DENIED;

(6) The Cross Motions for Summary Judgment filed by the State of Louisiana [ECF No. 49] and the Louisiana Primary Care Association [ECF No. 61] in Case No. 6:23-cv-1307 are GRANTED; all claims asserted in 6:23-cv-1307 are DISMISSED.

THUS DONE in Chambers on this 30th day of September, 2024.



ROBERT R. SUMMERHAYS
UNITED STATES DISTRICT JUDGE